



Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology
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31 December 2007

RE: AMP's Comments to NCI Draft Best Practices for Biospecimen Resources

AMP is an international not-for-profit educational society representing over 1,400 physicians, doctoral scientists, and medical technologists who perform molecular diagnostic testing based on nucleic acid technology. AMP members practice their specialty in widely diverse settings: academic medical centers, independent medical laboratories, community hospitals, federal and state health laboratories, and the *in vitro* diagnostic industry. In this capacity, AMP members are involved in every aspect of molecular diagnostic testing: administration and interpretation of molecular diagnostic tests, research and development, and education. For the last several years AMP has provided national leadership for the advancement of safe and effective practice and education for molecular diagnostic testing in the health care industry.

AMP's Mission Statement identifies the Society as "dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of genomics and proteomics." Our goal is to represent all members regardless of the setting in which they practice because they are united in the end intent to provide high quality, relevant information for the purpose of directing individual and patient community health management. We acknowledge, however, that different perspectives may emerge from those widely diverse settings. In those instances, our primary responsibility is to comment from the standpoint of molecular testing laboratories and the patients they serve.

Our comments are listed below:

B.1.2. We suggest the following edits in red. Biospecimen Collection and Processing.

"Biospecimen collection occurs in many contexts, including surgical procedures, organ donations and transplantation, autopsies, **bodily fluids (insert)**, and venipuncture:..."

B.1.2.1. To maintain the best quality of samples, the statement "rapid processing may not be as critical for other types of biospecimens, such as blood..." is not helpful. If bone marrow and peripheral blood are collected for liquid tumors, they also should be processed as quickly as possible to maintain cell integrity and gene/protein expression.

We suggest the following edits in red.

B.1.2.3.(new insert) If more than one specimen type or if specimens from more than one individual are processed at the same time procedures must be developed that prevent or minimize specimen cross-contamination.

B.1.4. We suggest the following edits in red. "...blood, serum, urine, **bone marrow and other bodily fluids (amniotic fluid surrounding a fetus, aqueous humour, bile, chyle, chyme, interstitial fluid, lymph, breast milk, mucus, pleural fluid, pus, saliva, semen, tears, vomit, feces, cerebrospinal fluid, and others)** (insert)

B.1.5.2. We suggest the following edits in red. ...Temperature-sensitive material is handled by a courier with resources to replenish the refrigerant in case of s shipping delay (ISBER 2005). **Proper shipping temperature must be verified at the time of specimen arrival and policy must be developed that will reject specimen if it is obvious that shipping temperature has not been maintained (e.g. gel packs are thawed, liquid nitrogen has evaporated, dry ice has evaporated)** (insert)

We suggest the following edits in red. ...Triple packaging is used for liquid samples. **Each liquid specimen must be packaged individually to prevent cross-contamination of individual samples if integrity of a storage container is compromised during shipping.** (insert)

Section B.3.2.3 – The document states that SOPs are reviewed at least every two years. We recommend that CAP guidelines be followed and that SOPs be reviewed at least every one year. (CAP Checklist Sept. 2007, MOL.29865: Is there documentation of at least annual review of all policies and procedures by the current director or designee? [<http://www.cap.org/apps/cap.portal> Accessed 18 Nov. 2007]).

In addition, similar CAP checklist items might also be beneficial for this document:

MOL.30095

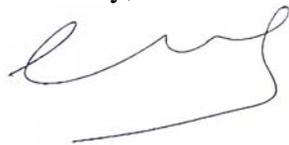
If there is a change in directorship, does the new director ensure (over a reasonable period of time) that laboratory procedures are well-documented and undergo at least annual review?

MOL.30210

When a procedure is discontinued, is a paper or electronic copy maintained for at least 2 years, recording initial date of use, and retirement date?

Thank you for the opportunity to comment on this very important document. AMP, members perform pharmacogenetic and heritable marker testing want to ensure the highest quality of laboratory testing for molecular pathology. Please do not hesitate to contact V.M. Pratt, PhD, AMP Clinical Practice Committee Chair at victoria.m.pratt@questdiagnostics.com if we can be of further assistance.

Sincerely,



Andrea Ferreira-Gonzalez, PhD
President